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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,290	06/20/2006	Helen Braven	ATLAS 9452 US	5797

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EXAMINER	
MARTIN, PAUL C	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,290	BRAVEN ET AL.	
	Examiner	Art Unit	
	PAUL C. MARTIN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-23 and 25-36* is/are pending in the application.

4a) Of the above claim(s) *32-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-23 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 19-23 and 25-36 are pending in this application, Claims 32-36 are acknowledged as withdrawn, Claims 19-23 and 25-31 were examined on their merits.

The objection to the Specification for failing to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for the reasons set forth on the attached "Notice to Comply" form has been provisionally withdrawn due to the Applicants' submission of a CRF and Sequence listing and the amendment to the Specification filed 06/30/08. At the time of writing this Office action, the CRF has not been checked for compliance.

The objection to the Specification for the improper use of trademarks has been withdrawn due to the Applicant's amendments to the Specification filed 6/30/08.

The rejection of pending Claims 19-23 and 25-31 under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention has been withdrawn due to the Applicant's amendments to the Specification filed 6/30/08.

The rejection of Claims 19 and 26 under 35 U.S.C. § 102(b) as being anticipated by Hugli (US 6,235,494 B1) has been withdrawn due to the Applicant's amendments to the claims filed 6/30/08.

The rejection of Claims 19, 20, 22 and 26 under 35 U.S.C. § 102(b) as being anticipated by Ludin *et al.* (US 6,495,336 B1) has been withdrawn due to the Applicant's amendments to the claims filed 6/30/08.

The rejection of Claims 19, 20, 22, 26, 28, 29 and 30 under 35 U.S.C. § 102(b) as being anticipated by Nagy *et al.* (2000) has been withdrawn due to the Applicant's amendments to the claims filed 6/30/08.

The rejection of Claims 19, 20, 21, 22, 26, 28 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Nagy *et al.* (2000) in view of Forrest *et al.* (US 4,978,610) has been withdrawn due to the Applicant's amendments to the claims filed 6/30/08.

The rejection of Claims 19, 20, 21, 22, 23, 26, 28 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Nagy *et al.* (2000) in view of Nicholson (US 4,456,337) has been withdrawn due to the Applicant's amendments to the claims filed 6/30/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19, 25, 26, 27 and 31 remain rejected under 35 U.S.C. § 103(a) as being obvious over Hugli (US 6,235,494 B1) in view of Braven *et al.* (US 2005/0221315 A1) for reasons of record set forth in the Prior Action.

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c).

This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 19, 20, 22, 24, 26 and 27 remain rejected under 35 U.S.C. § 103(a) as being obvious over Ludin *et al.* (US 6,495,336 B1) in view of Braven *et al.* (US 2005/0221315 A1) for reasons of record set forth in the Prior Action.

Claims 19, 20, 22, 25, 26, 28, 29 and 30 are newly rejected under 35 U.S.C. § 103(a) as being obvious over Nagy *et al.* (2000) in view of Braven *et al.* (US 2005/0221315 A1).

Nagy *et al.* teaches a method for detecting proline iminopeptidase (IP) activity in a sample solution by contacting the sample solution with the electrochemically labeled (linked to) IP substrates L-proline p-nitroanilide or L-proline 13-napthylamide under conditions suitable for IP to cleave the substrates and detecting the released p-nitroanilide or 13-napthylamide by the amperometric technique of cyclic voltammetry (Pg. 267, Schemes 1 and 2 and Pg. 268, Fig. 2) and wherein the level of IP activity is compared to a level of IP activity that is diagnostic of Bacterial (pathogen) Vaginosis (BV) a sexually transmitted disease, thereby detecting BV (Pg. 271, Column 1, Lines 1-15).

Nagy *et al.* does not teach a method wherein the electrochemically active marker is a metallocene (ferrocene) moiety.

Braven *et al.* teaches a compound wherein an amino acid, peptide or protein is labeled with electrochemically active ferrocene and wherein the compound is, or becomes electrochemically active following cleavage (Pgs. 19 and 20, Claims 75, 78, 85 and 89) and wherein each compound can be labeled with up to four metallocene groups (Pg. 6, Paragraph [0042]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the method for detecting the activity of the protease IP activity in a sample by contacting a sample solution with an IP substrate labeled (linked to) with an electrochemically active marker as taught by Nagy *et al.* above with the use of multiple electrochemically active ferrocene moieties as taught by Braven *et al.* because one of ordinary skill would have recognized that the ferrocene markers were as suitable for the purpose of electrochemical labeling of protein as the electrochemically active *p*-nitroanilide or β-napthylamide labeled protease substrates taught by Nagy *et al.* above. The MPEP states:

The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.,* 325 U.S. 327, 65 USPQ 297 (1945)

Claims 19, 20, 21, 22, 25, 26, 28, 29 and 30 are newly rejected under 35 U.S.C. § 103(a) as being obvious over Nagy *et al.* (2000) in view of Braven *et al.* (US 2005/0221315 A1) and further in view of Forrest *et al.* (US 4,978,610).

The teachings of Nagy *et al.* and Braven *et al.* were discussed above.

Neither Nagy *et al.* nor Braven *et al.* taught the use of differential pulse voltammetry to determine information about the electrochemically active marker.

Forrest *et al.* teaches that components which comprise an electroactively labeled reagent can be used in assays which measure a perturbation in the electrochemical characteristic of the components, and that this perturbation can be measured by differential pulse voltammetry, cyclic voltammetry or square wave voltammetry (Column 1, Lines 23-42).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Nagy *et al.* for detecting proline iminopeptidase (IP) activity in a sample solution by cyclic voltammetry by using differential pulse voltammetry as taught by Forrest *et al.* because they are art-recognized functionally equivalent techniques for measuring electrochemical activity.

The use of alternatives and functional equivalent techniques would have been desirable to those of ordinary skill in the art based upon the economics and availability of detection apparatus as well as artisinal preference. There would have been a reasonable expectation of success in making this substitution because Nagy *et al.* teaches the use of cyclic voltammetry to measure electrochemical characteristics and Forrest *et al.* teaches that both differential pulse voltammetry and cyclic voltammetry can be use to measure electrochemical characteristics.

Claims 19, 20, 22, 23, 25, 26, 28, 29 and 30 are newly rejected under 35 U.S.C. § 103(a) as being obvious over Nagy *et al.* (2000) in view of Braven *et al.* (US 2005/0221315 A1) and further in view of Nicholson (US 4,456,337).

The teachings of Nagy *et al.* and Braven *et al.* were discussed above.

Neither Nagy *et al.* nor Braven *et al.* taught wherein the information relating to the electrochemically active marker is determined using a technique that requires one or more electrodes that are functionally surrounded by a selectively permeable membrane.

Nicholson teaches a technique wherein two or more electrodes are functionally surrounded by a selectively permeable membrane which prevents loss of electrochemically generated reactant species as well as preventing contamination of the counter electrodes where these species could interfere with the counter electrodes (Column 6, Lines 6-35).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the combined method of Nagy *et al.* and Braven *et al.* for detecting proline iminopeptidase (IP) activity in a sample solution by cyclic voltammetry by using a technique wherein two or more electrodes are functionally surrounded by a selectively permeable membrane as taught by Nicholson because the selectively permeable membrane would serve to prevent contamination of the electrodes from interferants, both exogenous and endogenous to the assay. One of ordinary skill in the art would have been motivated to make this modification because of the advantages discussed by Nicholson such as preventing loss of electrochemically generated reactant species into the mixture milieu as well as serving to minimize contaminants interacting with the electrodes entering from the milieu. There would have been a reasonable expectation of success in making this modification because both techniques are drawn to the detection of electrochemically active components using multiple electrodes.

Response to Arguments

Applicant's arguments filed 06/30/08 have been fully considered but they are not persuasive.

The Applicant notes that the instant application claims priority to GB 0316075.1, filed 07/09/2003 and that Braven *et al.* (US 2005/0221315 A1) is a National phase patent Application filed under 35 U.S.C. § 371 of WO 2003/074731, published 12 September 2003 and does not therefore qualify as Prior Art (Remarks, Pg. 21, Lines 12-20).

This is not found to be persuasive for the following reasons. The Braven *et al.* reference is a 371 of PCT/GB03/00613 which was **filed on February 11, 2003**, not November 02, 2003 as argued in the response**.** As Applicant is no doubt aware, as the international Application (PCT) was in English, designated the US and was filed on or after November 29, 2000, the § 102(e) date is the international filing date. The reference predates the instant application's Priority by at least four months and therefore qualifies as a valid reference under 35 U.S.C. § 103(a).

Conclusion

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL C. MARTIN whose telephone number is (571)272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

09/24/08

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657